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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,547	08/08/2001	Andrew Grupe	ROCH-007	4701

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EXAMINER	
PARAS JR, PETER	
ART UNIT	**PAPER NUMBER**
1632	10

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,547	GRUPE ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-22 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 8-11, drawn to a method of treating a subject having a disease state associated with a mucus secretion disorder, wherein the disease state is associated with mucus hypersecretion, classified in class 424, subclass 184.1.

II. Claims 1, 6-7, and 8-11, drawn to a method of treating a subject having a disease state associated with a mucus secretion disorder, wherein the disease state is associated with mucus hyposecretion, classified in class 424, subclass 184.1.

III. Claims 12 and 14-15, drawn to a method of screening for a compound that modulates CaCC activity in a cell free system, classified in class 435, subclass 4.

IV. Claims 12-15, drawn to a method of screening for a compound that modulates CaCC activity in a cell, classified in class 435, subclass 7.21.

V. Claims 12-15, drawn to a method of screening for a compound that modulates CaCC activity on a solid support, classified in class 436, subclass 518.

VI. Claims 16-17, drawn to an unidentified compound, are unclassifiable as the compound is unknown.

VII. Claims 18-21, drawn to a transgenic non-human animal comprising an altered CaCC gene, classified in class 800, subclass 13.

VIII. Claim 22, drawn to method of detecting expression of CaCC in a sample with a polynucleotide, classified in class 435, subclass 6.

IX. Claim 22, drawn to method of detecting expression of CaCC in a sample with an antibody, classified in class 435, subclass 7.1.

Inventions I-V and VIII-IX are patentably distinct each from the other. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods that have different modes of operation and different effects. The claimed methods are materially different, requiring different reagents and different technical considerations. For example, the method of Group I is directed to a method of treating s subject having a disease state associated with a mucus secretion disorder, wherein the disease state is associated with mucus hypersecretion; the method of Group II is directed to a method of treating s subject having a disease state associated with a mucus secretion disorder, wherein the disease state is associated with mucus hyposecretion; Groups III-V are directed to screening methods to identify compounds that modulate CaCC activity, wherein the assay is performed in a cell free system, in a cell, or on a solid support, respectively; Groups VIII-IX are directed to methods of detecting expression of CaCC in a sample, wherein expression is detected with a

polynucleotide or an antibody, respectively. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are chemically different products that have different modes of operation, different functions, and different effects. For example, the transgenic non-human animal of Group VII can be used as a disease model while the unknown compound of Group VI can be used to modulate CaCC activity. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions [I-V and VIII-IX] and [VI-VII] are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are products and methods that have different modes of operation as they can be used separately from each other. The products of Groups VI-VII can be used in materially different methods from the methods of Groups I-V and VIII-IX while the methods of Groups I-V can be practiced with chemically different products from the products of Groups VI-VII. The transgenic

non-human animal of Group VII can be used to produce antibodies against an antigen, while the methods of Groups I-II require a subject having a disease state associated with a mucus secretion disorder; the methods of Groups III-V are directed to screening methods to identify compounds that modulate CaCC activity, wherein the assay is performed in a cell free system, in a cell, or on a solid support; and the methods of Groups VIII-IX are directed to methods of detecting expression of CaCC in a sample, wherein expression is detected with a polynucleotide or an antibody. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER